

REMARKS**A. Introductory Remarks**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

Upon entry of the foregoing amendments, claims 9, 11-13 and 16-18 will be pending in this application. Claims 10 and 15 are presently cancelled. Claims 9 and 13 are presently amended. Claim 18 is presently added. As described below, support for new claim 18 exists at page 11, lines 1-2 of the specification, as filed.

B. The Claims Comply with the Enablement Requirement of 35 U.S.C. § 112, First Paragraph

Claims 9-17 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable one skilled in the art to practice the full scope of the claimed invention without engaging in undue experimentation. Although the Examiner acknowledged that the specification is "enabling for: a method of inhibiting synovial cell growth comprising administering an antibody produced by FERM BP-2998 [PM-1]," he stated that the enablement does not extend to antibodies "including a set of complementarity determining regions of . . . FERM BP-2998" because CDR-grafted antibodies are "complex and unpredictable."

Without acquiescing to the enablement rejection, and solely to advance prosecution, Applicants have limited the claims to methods that comprise administering humanized PM-1 antibody. In that regard, Applicants also have added claim 18, which depends from claim 9 and recites particular characteristics of a humanized PM-1 antibody. The specification contains exemplary support for administering humanized PM-1 in the paragraph bridging pages 10-11.¹ In connection with the addition of claim 18, Applicants have amended the paragraph bridging pages 10-11 to explicitly describe the characteristics of a particular

¹ This portion of the specification references WO 92/19759, which provides detailed instructions on how to make humanized PM-1 antibodies. Since the present application was drafted, U.S. Patent 5,795,965, which is based on WO 92/19759 has issued. The '965 patent contains claims directed to humanized IL-6 antibodies, including hPM-1 (claim 3).

humanized PM-1 antibody. This description previously was incorporated by reference to WO 92-19759.

The specification's reference to WO 92/19759 does not negative enablement because a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

As amended, the claims conform in scope to what the Examiner already has deemed enabled: a particular type of IL-6 antibody explicitly described in the specification. Therefore, Applicants respectfully request withdrawal of the rejection. However, Applicants intend to pursue claims directed to the full scope of their enabled invention in a continuing application.

C. The Claims Comply with the Written Description Requirement of 35 U.S.C. § 112, First Paragraph

Claims 9-17 were newly rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not contain a written description of the claimed invention. Specifically, the Examiner stated that the specification does not adequately describe "an antibody including a set of complementarity determining regions of an antibody produced by FERM BP-2998."

As amended, the claims no longer contain the recitation to which the Examiner objected. Accordingly, Applicants respectfully request withdrawal of the rejection.

D. Concluding Remarks

The present application is now in condition for allowance, and favorable reconsideration of it, as amended, is respectfully requested.

If the Examiner believes that an interview would advance prosecution of the application, he is invited to contact the undersigned by telephone.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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